

NRC INSPECTION MANUAL

PART 9900: 10 CFR GUIDANCE

50B_VIIC.CFR

10 CFR 50, APPENDIX B, VII GUIDANCE - USE OF CERTIFICATE OF CONFORMANCE

A. PURPOSE

To identify specific criteria which should be used by Inspection and Enforcement personnel for the review and evaluation of licensee management control systems pertaining to the use of certificates of conformance in lieu of original records.

B. DISCUSSION

10 CFR 50, Appendix B, Criterion VII requires that documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear power plant prior to installation or use of such material and equipment.

Experience has shown that in reviewing IE Circular 78-08 and other Bulletins, some licensees have not effectively implemented the requirements of Criterion VII, and equipment is being received and installed that either does not conform to the procurement documents or the documented evidence that is required prior to use does not exist or is not adequate to establish that the equipment meets requirements.

One of the principal problems has been the misuse of the certificates of conformance by the licensee and the supplier. Several root causes for this misuse appear to be: (1) inadequate specification in the procurement document relative to acceptance of the item, (2) inadequate audits or independent inspections by the licensee or his agent to assure validity of certificates of conformance, (3) inadequate evaluation of quality documentation to assure that it does establish that equipment received meets requirements, (4) inadequate practice of accepting complicated engineered items solely on certificate of conformance documentation.

ANSI N45.2.13-1976 (or 1974 draft in WASH-1309), as supplemented or modified by Regulatory Guide 1.123, provides the minimum criteria to be satisfied during the preparation of procurement documents, surveillance of suppliers and acceptance of the item or service to assure adequate control over purchased items.

The certificate of conformance system for acceptance of purchased items represents one option that a purchaser may select to assure the item meets specified requirements. However, as discussed under Section 10.3.3 of ANSI N45.2.13, the use of certificate of conformance, by itself, for acceptance of the item is limited to items of simple design and those which involve standard

materials, processes, and tests. Therefore, for complex engineered items other documentation in addition to a COC may be required to provide assurance that the item meets requirements unique to nuclear power plants. In any case, what is required for acceptance of an item should be established (in the procurement document or appropriate procedures) and be made known to the receiving inspection function. Where a certificate of conformance is used solely, or in part, as the means to assure specified requirements are met, the criteria of ANSI N45.2.13 Section 10.2 should also be met. Examples as to the types of controls deemed appropriate include: (1) the certification system, including the procedures to be followed in filling out a certificate and the administrative procedure for review and approval of the certificates (including the identification of the function and the manager thereof responsible for approval of certificates), should be described in the Purchaser's/Supplier's quality assurance program, (2) means should be provided to verify the validity of Supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification should be commensurate with the Suppliers' past quality performance and safety significance of the purchased item.

Commonly used certifications are manufacturer's certifications that a standard material (usually consumables, such as weld rod and fly ash), if tested, would exhibit the product characteristics shown on the certification document. A typical certification of this type is acceptable only if the using agency can demonstrate¹ that the product was manufactured under a process control system which provides for product control and process records which can establish that the product was manufactured within the characteristic limits identified on the typical certification.

Acceptance review of quality documents by or for the licensee should be accomplished by suitably indoctrinated and trained personnel, that is, personnel appropriately trained in the area being reviewed.

The IE inspector should determine whether the licensee performs meaningful review of their policies relative to the use of and in verifying the validity of certifications.

In addition, where a purchaser upon receipt or following use of a purchased item finds a deviation from specified requirements which has not been previously identified on the supplier documentation, the IE inspector should assure himself that the licensee has identified a need to re-audit the suppliers system of verifying that specified requirements are met before signing the COC.

END

¹ Either by the using agency approving the process control method or by performing audits to demonstrate that the required process controls are adequate.